

Section 01: Study Title and Research Personnel

Selecting the Campus Oversight Organization:

To select the Campus Oversight Organization as your review unit, you must answer “**Yes**” to the last question under CRU (Clinical Research Unit) Selection: “**Does this study require CRU oversight for any other reason not listed above?**” Next, Choose “**Campus Oversight Organization**” in the dropdown menu below.

Note that you still will include your department/institute as the “Study Organization” but this department will not need to provide oversight for the eIRB application.

Other general tips:

If desired, the study coordinator and regulatory coordinator can be the same person.

As noted in eIRB, it is not recommended to have Co-Principal Investigators, as this can slow down the review process. Other Investigators may be included as key personnel and you may choose if they have edit rights and receive emails from eIRB when updates are made.

Key personnel should include:

- Anyone involved in the consent process
- Anyone involved in recording/processing identifiable PHI

Note that all key personnel must successfully complete CITI and DHRT training requirements.

01. Study Title and Research Personnel

User Guide

* Short Title:	Key words or phrases that can be used to quickly identify the study. Once a short title is chosen it cannot be changed.
* Full Title:	Full title of the study.
* Study Organization:	The Department or Division that takes responsibility for the study. This is usually the Primary Department of the Principal Investigator, or if the PI is not Duke faculty, the Department of the Duke Faculty Sponsor.
CRU (Clinical Research Unit) Selection: * Is Duke University Hospital, Durham Regional Hospital, Duke Raleigh Hospital, any Duke Clinic or any other Duke Medicine entity a site where interventions or interactions with research subjects will occur as part of this study? <input type="radio"/> Yes <input type="radio"/> No Clear * Will a Duke faculty or staff member be involved with interventions, observations, surveys or interactions with Duke patients? <input type="radio"/> Yes <input type="radio"/> No Clear * Does this study involve the use of biological specimens from Duke patients? <input type="radio"/> Yes <input type="radio"/> No Clear * Does this study involve access to confidential, private information from Duke patients? <input type="radio"/> Yes <input type="radio"/> No Clear * Does this study require CRU oversight for any other reason not listed above? <input checked="" type="radio"/> Yes <input type="radio"/> No Clear Select the CRU to which this study belongs: Campus Oversight Organization	The Clinical Research Unit that takes responsibility for this study. More information on CRUs can be found on the Duke Office of Clinical Research (DOCR) website: http://docr.som.duke.edu Questions concerning CRU selection should be directed to docr.help@dm.duke.edu

YES

Campus Oversight Organization

Note: Only people with current Human Subjects Protection (HSP) certification appear on the Select Person lists. If you cannot find the person, go to the FAQ section of the eIRB Home page and click the link *I'm trying to add someone to my study, but I can't find their name*.

<p>* Principal Investigator:</p> <input type="text"/> <input type="button" value="Select..."/>	<p>Investigator responsible for the conduct of the study at Duke.</p>										
<p>Primary Study Coordinator (CRC):</p> <input type="text"/> <input type="button" value="Select..."/>	<p>If the study has multiple coordinators, this person is the primary contact regarding enrollment logs, subject billing and clinical issues.</p>										
<p>Primary Regulatory Coordinator:</p> <input type="text"/> <input type="button" value="Select..."/>	<p>If the study has multiple coordinators, one must be the primary contact person for the IRB and anything regarding regulatory issues.</p>										
<p>Co-Principal Investigators:</p> <input type="text"/> <input type="button" value="Add"/> <table border="1" data-bbox="248 422 997 464"> <thead> <tr> <th data-bbox="248 422 487 443">First Name</th> <th data-bbox="487 422 730 443">Last Name</th> <th data-bbox="730 422 997 443">Department</th> </tr> </thead> <tbody> <tr> <td colspan="3" data-bbox="248 443 997 464">There are no items to display</td> </tr> </tbody> </table>	First Name	Last Name	Department	There are no items to display			<p>Co-Principal Investigators act in the same capacity as the Principal Investigator, sharing equal responsibility. Other Investigators should be added under 'Other Key Personnel' below. It is recommended that a study have only one Principal Investigator to help expedite workflow.</p>				
First Name	Last Name	Department									
There are no items to display											
<p>Other Key Personnel:</p> <input type="button" value="Add"/> <table border="1" data-bbox="248 506 997 546"> <thead> <tr> <th data-bbox="248 506 438 527">Name of Individual</th> <th data-bbox="438 506 568 527">Role on study</th> <th data-bbox="568 506 682 527">Edit Rights</th> <th data-bbox="682 506 812 527">Receive Email</th> <th data-bbox="812 506 997 527">CITI Expiration</th> </tr> </thead> <tbody> <tr> <td colspan="5" data-bbox="248 527 997 546">There are no items to display</td> </tr> </tbody> </table>	Name of Individual	Role on study	Edit Rights	Receive Email	CITI Expiration	There are no items to display					<p>Key Personnel are research personnel who are directly involved in conducting research with human subjects, or who are directly involved with the handling of identifiable private information related to those subjects, including protected health information, in the course of a research project.</p>
Name of Individual	Role on study	Edit Rights	Receive Email	CITI Expiration							
There are no items to display											